



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,106	08/20/2003	Johan F.M. Gijssbers	11738.00120	6509
70/467 7590 05/06/2008 BANNER & WITCOFF, LTD AND ATTORNEYS FOR CLIENT NUMBER 011738 10 SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			EXAMINER WACHTEL, EMILY L	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 05/06/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,106

Applicant(s)

GIJSBERS ET AL.

Examiner

EMILY WACHTEL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 25, 27-31, 33-35, 37-43 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 29-31, 33-35, 37-43, 45-48, and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 29-31, 33-35 and 37-43 and 45-48 are objected to because of the following informalities: Independent claim 29 claims "a system" whereas dependent claims 30-35 and 37-48 claim "the apparatus".

Appropriate correction is required.

2. Claim 29 is objected to because of the following informalities: There is insufficient antecedent basis for limitation "the brain fluid" in part d.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500).

With regard to claim 23, With regard to claim 29 Osterholm teaches a system for controlling epileptic seizures comprising: a) a brain fluid pumping mechanism (Figure 13 the pumping mechanism is taken to encompass all individual pumps contributing to the fluid pumping in this instance pump 111 is being considered, Col. 12 lines 17-19), having an input, coupled to a patient's brain for extracting brain fluid, and having an output (Figure 13 input is

connected to the nutrient emulsion reservoir 100 - a source other than the patient's brain and an output connected to the chemical balancing unit 110); b) a fluid ion adjustment mechanism coupled to said output of said brain fluid pumping mechanism (In Figure 13 the ion adjustment mechanism is taken to be the chemical balancing unit 110, it is connected to the output of pump 111. Further in Figure 1, fluid from the brain is monitored for potassium and sodium ion concentrations - monitor 34 Col. 13 lines 46-50, in this diagram chemical balancing, taken to be ion adjustment, is at unit 12. Col. 15 lines 38-41 - sodium, potassium, calcium, magnesium, and chloride ions are balanced in the nutrient emulsion, it is taken that these ions would be balanced in the chemical balancing unit.), said fluid ion adjustment mechanism having an output from which modulated ion-content fluid is produced (Figure 13 - the balanced fluid is returned to the nutrient emulsion reservoir 100); c) a catheter, having an input coupled to the output of said ion adjustment mechanism and having an output inserted into a predetermined region of a patient's brain (Figure 13 - catheter 120 is connected to the nutrient emulsion reservoir which is the output for the fluid from the ion adjustment mechanism and is output into the patient's brain, Col. 12 lines 30-31 and 34-35), whereby brain fluid is extracted from a patient's brain, ion-concentration of said fluid is adjusted and said brain fluid is re-injected into said brain (fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored, controlled, and re-injected, Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d).

Osterholm does not specifically disclose computer control with stored programming which controls the pumping mechanism. However, Osterholm does disclose that the device uses pumping mechanism which are 'on line' and a closed loop process (Col. 12 lines 14-16). Further Osterholm discloses that the pump can be automatically shut down in response to an alarm (Col.

14 lines 39-42). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses the pump being on line and using closed loop control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

With regard to claim 25, Osterholm teaches a catheter used to withdraw fluid from the brain (Fig. 1 catheter 30), this catheter is taken as a probe which ultimately provides an output related to the measurement of ion-concentration of the brain as the fluid which is withdrawn via the probe is monitored (Fig. 1 output monitor 34). Further, Osterholm teaches chemical control which balances ion concentrations, Col. 14 lines 60-66, Col. 15 lines 38-41). Osterholm does not specifically disclose computer control. However, Osterholm does disclose an alarm which may automatically disable the system in the event of chemical imbalance (Col. 15 lines 1-4) and that chemical balancing is done in a closed loop process (Col. 12 lines 13-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses automatic chemical balancing control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

5. Claims 27 and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) as applied to claim 5 above, and further in view of applicant admitted prior art (AAPA).

With regards to claims 27 and 28, Osterholm discloses a system substantially as claimed. Osterholm does not specifically disclose using a membrane potential equation. However, AAPA discloses using the Goldman equation as a well-known equation for calculating the membrane potential (Page 9 [23]), therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to calculate the ion concentration using such a membrane potential equation in the device in Osterholm because APPA teaches it is an art recognized means for monitoring the ion concentration so the system can determine how the fluid needs to be chemically balanced.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of applicant admitted prior art (AAPA) and further in view of Lucido et al. (U.S. Patent 6,402,941).

With regard to claim 49, Osterholm teaches a device which re-circulates fluid through the brain which is chemically balanced and filter (Col. 14 lines 61-62, chemical balancing Fig. 1 unit 12). The device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid. However, AAPA discloses that using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use filtering or chemical treatment to balance the ion concentration in the device of Osterholm because AAPA teaches it is an art recognized

means for doing so in order to balance the fluid to the appropriate desired ion concentration. In the device of Osterholm fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored and controlled (Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). It is pumped into a localized region of the patient's brain in the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35). Further, in the device of Osterholm fluid that was injected into the brain circulates and then is withdrawn and monitored, effectively the brain fluid proximate to the region where the fluid in Osterholm is injected is monitored (Col. 13 lines 44-47). Osterholm teaches the fluid is monitored for ion concentrations however, Osterholm does not disclose a means for monitoring as in how the monitoring device actually monitors the ion concentration. However, as a means for monitoring, Lucido teaches a conductivity sensor which measures ion concentration (Col. 8 lines 42-43). It would have been obvious to a person of ordinary skill at the time the invention was made to use conductivity as a means for monitoring ion concentration in the device of Osterholm because Lucido teaches it is a known method of measuring ion concentrations and would yield the predictable result of measuring the ion concentration so that the device of Osterholm can monitor them.

Allowable Subject Matter

7. Claim 29-31, 33-35, and 37-43, and 45-48 are objected to but would be allowable pending correction. The prior art of record does not teach or otherwise render obvious a fluid pumping mechanism with means for adjusting the delivery of the modulated ion-content fluid based upon the measured electrical conductivity of the brain fluid. Claim 50 is objected to as

being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

8. Claims 24 and 36 have been canceled. Claims 23, 29, 37, and 39 stand amended. The amendments to the specification and the abstract have been entered.

Response to Arguments

9. Applicant's arguments filed March 6, 2008 have been fully considered but they are not persuasive. With regard to claim 49, the applicant's arguments were based on limitations added to claim 29. However, claim 49 does not depend from claim 29 and, therefore, the arguments are not applicable.

10. Applicant's arguments/amendment with respect to claims 23, 25, and 27-28 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

11. The terminal disclaimer filed on March 6, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,551,301 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571)270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767